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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,913

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Matthew S. Solar

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10/02/2006

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/671,913

Applicant(s)

SOLAR ET AL.

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 8-28 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10, 13, 24, 26-28 and 30-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 9, 11-12, 14-23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a); Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/03 and 8/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, Species III in the reply filed on 05 September 2006 is acknowledged. The traversal for Group I is on the ground(s) that the product as claimed cannot be made by a materially different process since "forming" as used in some of the pending claims is intended to encompass all manufacturing methods. This is not found persuasive because the plain meaning of the term "forming" as used in some of the pending claims does not encompass the manufacturing method blow molding or extrusion, for example. The traversal for Species III is on the ground(s) that at least claim 1 is generic. This is not found persuasive because Figures 1A-C clearly show the base unit lacks the standoff features recited in claim 1.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 8, 13, 24, 26-28, and 30-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Contrary to applicant's remark, claim 10 reads on nonelected species IV, therefore, claim 10 is also withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species. Applicant timely traversed the restriction (election) requirement in the reply filed on 05 September 2006.

Drawings

3. The drawings are objected to because some of the claimed features are not visible due to the black background. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid

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abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 156 in Figure 1B, 138 in Figure 1C, 232 in Figure 2, and 342 in Figure 3A. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing

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sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR

1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities: page 11, line 25, contains an incorrect reference numeral. Replace "240" with --340--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 6, 9, 11, 16-17, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mowlai-Ashtiani (Patent No. 6,110,182).

See Figure 1 for structural limitations: guide portion (72), spherical portion (32), base unit (80) having a deformable socket (10; via attachment 78; column 3, lines 45-51), actuating device (52), three relief openings (20, 22, and 24), and a screw retention feature (not labeled; the portion surrounding the two visible screws on base unit 80).

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The extensions attached to the base unit (80) and the portion that extends behind the neck of the patient that is inherently capable of mounting the base unit to both sides of the skull (working surface) via a securing device (screw; not labeled) form the “number of standoff features” (2 sides) that mount the spherical socket above the work surface to provide access beneath the spherical socket. The portion of the standoff feature (the portion with the screw) that is inherently adapted to contact the work surface (via the flat side) is circular, therefore, capable of contacting the work surface along a circle. The opposing side that does not contact the work surface comprises the “shelf” portion.

Mowlai-Ashtiani further discloses the device provides symmetric tightening of the spherical socket around the spherical portion (column 2, lines 15-18 and 50-54).

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mowlai-Ashtiani in view of Hennig (Patent No. 6,328,748 B1).

Mowlai-Ashtiani discloses an actuating device as described above, but does not disclose the actuating device includes a threaded locking ring. Hennig teaches a threaded locking ring (Figure 1, element 3) adapted to engage a number of threads (9) coupled to the spherical socket (1; column 5, lines 45-47). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide threads on the spherical socket and a threaded locking ring to engage the threads on the socket of Mowlai-Ashtiani, as taught by Hennig, in order to hold the spherical portion while providing the best possible range of movement for instruments (column 5, lines 45-50).

11. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mocarski (Patent No. 3,073,310) in view of Mowlai-Ashtiani.

Mocarski discloses a base unit (Figure 2, element 11), three standoff features (13), and a securing device (14). Mocarski does not disclose the base unit has a deformable spherical socket. Mowlai-Ashtiani teaches a guide portion (72), spherical portion (32), base unit (80) having a deformable socket (10; via attachment 78; column 3, lines 45-51), actuating device (52), and three relief openings (20, 22, and 24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the spherical socket device taught by Mowlai-Ashtiani to the base unit of Mocarski in order to provide the user with a greater range of motion, in turn allowing the surgical instrument

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inserted therein to be accurately aligned with the target within the patient's skull (column 4, lines 48-56).

12. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mocarski in view Mowlai-Ashtiani and further in view of Ghajar et al. (Patent No. 4,998,938).

Mocarski in view Mowlai-Ashtiani disclose the standoff features are truncated (the portion against the skull is parallel to the portion attached to the base), but does not disclose the standoff features are cone shaped. Ghajar et al. teach cone shaped standoff features (wider on top and narrower towards the bottom). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize cone shaped standoff features as taught by Ghajar et al. in order to support the base unit (via the large surface area) and minimize contact with respect to the patient's scalp and cranium (via the smaller surface area) during the procedure, thus reducing the risk of infection to the surrounding tissue (column 2, lines 44-48).

13. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mowlai-Ashtiani.

Mowlai-Ashtiani discloses a screw retention feature (see rejection above), but does not disclose expressly that the screw retention feature includes an elastomer band, a protruding structure, or that it may be located above a screw opening. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to utilize an elastomer band, a protruding structure, or a retention feature that may be located above a screw opening.

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There are numerous retention features well known in the art and Applicant has not disclosed that an elastomer band, a protruding structure, or a retention feature that may be located above a screw opening provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the screw retention feature shown in Figure 1 because the function of the feature is to keep the screws from falling out of the base unit and Figure 1 shows the retention features of Mowlai-Ashtiani perform this function. Therefore, it would have been obvious to one of ordinary skill in the art to modify Mowlai-Ashtiani to obtain the invention as specified in claims 18-20.

14. Claims 22, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mowlai-Ashtiani in view of Hennig.

See rejections above for the same structural limitations as claims 1, 9, 11 and 17. Mowlai-Ashtiani does not disclose an insert. Hennig discloses an insert (Figure 5, element 17) located within a longitudinal opening (10). Figure 1 shows the outer diameter is similar to that of the guide (11), thus fits closely with the opening (10). The inner diameter fits closely with a device to be guided ("specially adapted to" column 6, lines 35-36). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize an insert as taught by Hennig in order to size the longitudinal opening in the longitudinal guide with the specific equipment that is to be passed there through (column 6, lines 35-36). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to size the insert to fit closely with a

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biopsy probe in order to adapt to the probe utilized with the device of Mowlai-Ashtiani (column 4, lines 31-34).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 7:30 a.m. - 5:00 p.m., alternate Fridays 7:30 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson *MT*
September 22, 2006

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SUPERVISORY PATENT EXAMINER
9/22/06